Citation:

St-Onge, M.P., Goree, L.L., Gower, B. High-milk supplementation with healthy diet counseling does not affect weight loss but ameliorates insulin action compared with low-milk supplementation in overweight children. *The Journal of Nutrition* 2009; 139(5): 933-938.

PubMed ID: 19321584

Study Design:

Randomized controlled trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To test whether high-milk consumption in children who are low-milk drinkers would lead to greater weight loss and improvements in metabolic risk factors than low-milk consumption as part of a healthy eating diet for 16 weeks.

Inclusion Criteria:

- Low-milk and low-calcium consumers (consuming ≤1 serving of milk per day and <600 mg calcium daily)
- Above the 95th percentile for BMI for age and waist circumference above the 95th percentile for age or BMI within the 85th-95th percentile range and if a child had parent with type 2 diabetes or the child had fasting serum insulin concentrations ≥173.6 pmol/L
- Parent provided informed consent and child provided assent.

Exclusion Criteria:

- Milk consumption >1 serving of milk per day
- Calcium intake >600 mg per day
- BMI below the 95th percentile for age and waist circumference below 95th percentile for age or BMI less than 85th percentile for age and no parental history for type 2 diabetes or child with fasting serum insulin concentrations <173.6 pmol/L.

Description of Study Protocol:

Recruitment

- All recruitment efforts took place in Jefferson County and Shelby County areas around Birmingham, Alabama

- Advertisement via flyer and newspaper advertisements, presence of investigators at health fairs and summer day camps and discussion of the study on a radio show
- Two step screening process with initial screening completed over the phone to assess eligibility and interest and second screening conducted in-person

Design: randomized controlled trial

Intervention

- Randomized to either high-milk or low-milk consumption with beverages dispensed by the General Clinical Research Center Bionutrition unit on a weekly basis
    - High-milk consumption group
        - Counseled to consume three 236 ml servings of skim milk and one 236 ml serving of 1% low fat chocolate milk per day
    - Low-milk consumption group
        - Counseled to consume three 200 ml servings of sugar-sweetened beverage daily, four 236 ml servings of skim milk per week and five 236 ml servings of 1% chocolate milk per week
- Dietary counseling on healthy eating provided at baseline and week one, two, four, six, eight and 12

Statistical Analysis

- Metabolic data were analyzed by fitting linear mixed models
- Body composition data from the MRI analyses were analyzed to examine differences in change in total adipose tissue, subcutaneous adipose tissue, visceral adipose tissue, intermuscular adipose tissue and muscle mass
- Changes from baseline within each group examined using unpaired t tests
- P values of <0.05 were considered significant.

Data Collection Summary:

Timing of Measurements

- Height and weight measurements obtained at each dietitian visit at week zero, one, two, four, six, eight, 12 and 16
- Waist and hip circumferences obtained at week zero, four, eight, 12 and 16
- MRI used to quantify whole-body adipose tissue and muscle content and distribution conducted at baseline and endpoint
- Blood pressure measurements taken while in seated position obtained at baseline and week four, eight, 12 and 16
- Fasting blood samples obtained at baseline and week four, eight, 12 and 16 and analyzed for total lipid profile, glucose insulin and leptin
- Oral glucose tolerance test (OGTT) conducted at baseline and endpoint
- Dietitian review of 24 hour food recall completed at baseline and week one, two, four, six, eight, and 12 in order to assess child's compliance with diet and identify areas for improvement

Dependent Variables

- Weight change
- Change in body composition: MRI used to quantify whole body adipose tissue and muscle content as well as distribution (total adipose tissue (TAT), subcutaneous adipose tissue (SAT), visceral adipose tissue (VAT), intermuscular adipose tissue (IMAT), and muscle mass
- Change in metabolic variables
    - Blood pressure, serum lipids, glucose and insulin

Independent Variables

- Level of milk consumption, time, and time by beverage interaction

Control Variables

- Extra-energy beverage consumption
- Food intake and diet compliance.

Description of Actual Data Sample:

Initial N: 55 children (11 males, 44 females)

Attrition (final N): 45 children (nine males, 36 females)

Age:

- All children: 9.4±0.8 years
- High-milk consumption group: 9.2±0.8 years
- Low-milk consumption group: 9.6±0.8 years

Ethnicity:

- 29 African-American subjects
- 25 Caucasian subjects
- One subject categorized as other

Other relevant demographics: None

Anthropometrics: No significant difference ($p \geq 0.05$) among groups for weight, height, BMI and waist circumference

Location: University of Alabama at Birmingham, Alabama.

Summary of Results:

Key Findings:

- Children in both groups increased in weight and height ($p<0.0001$) while tending to reduce BMI ($p=0.057$)
- Time and the time x beverage interaction did not affect waist circumference, percent body fat, and BMI
- The beverage tested ad the beverage x time interaction did not affect any of the body

composition variables measured using MRI
- Effects of time on skeletal muscle ($p<0.0001$) and VAT ($p=0.003$)
- Effects of age on total body volume ([=0.03), skeletal muscle ($p=0.008$), SAT ($P=0.007$) and TAT ($p=0.008$)
- Effects on race on total body volume ($p=0.009$), skeletal muscle ($p=0.001$), SAT ($p=0.014$), IMAT ($p=0.001$), VAT ($p=0.003$) and TAT ($p=0.023$)
- Caucasians had lower body volume, lower SAT and lower TAT but higher VAT than African-Americans
- The beverage tested and the beverage x time interaction did not affect any of the metabolic variables (blood pressure, serum lipids, glucose and insulin) measured in fasting children
- There was a beverage x time interaction on insulin AUC as assessed with an OGTT ($p=0.044$)
- High-milk consumption leads to lower insulin AUC than low-milk consumption
- Beverage, time and beverage x time interaction did not affect glucose AUC

Body Compartment	High- milk group	Low-milk group
Total body MRI	0.20±0.83	1.03±0.45
Skeletal muscle	0.50±0.20	0.69±0.09
SAT	-0.36±0.54	-0.13±0.29
IMAT	-0.02±0.09	-0.01±0.02
VAT	-0.18±0.08	-0.11±0.05
TAT	-0.56±0.62	-0.25±0.32

Other Findings

- Consumption with study beverage consumption was excellent
  - Children in high-milk group reported consuming ~98% of the skim milk and 98.5% of the chocolate milk
  - Children in low-milk group reported consuming 96.4% of the skim milk, 97% of the chocolate milk and 99.5% of the sugar sweetened beverage
  - Consumption of extra-energy beverages averaged 3.4 and 4.3 serving over the 16 week period in the high and low-milk groups respectively.

Author Conclusion:

Findings show a lack of effect of high-milk consumption (four servings of milk per day) on changes in body weight or body composition compared with low-milk consumption (one serving of milk per day). A major finding is that, as part of a healthy eating diet in overweight children, high-milk consumption leads to lower insulin AUC than low-milk consumption. This may have implications for the prevention of diabetes development in overweight, at-risk children.

Reviewer Comments:

- *Level of compliance with Stoplight diet not discussed although dietitian conducted food recall*
- *1:4 ratio of boys to girls therefore results may not be generalize to boys*

- *Subject reported compliance to study beverage consumption.*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes
Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	No
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes

3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	Yes
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes

6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	No
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	Yes
6.6.	Were extra or unplanned treatments described?	Yes
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	???
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	Yes
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes

8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	No
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes